



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,723	01/29/2001	Peter G. Webb	10010016-1	1312

7590 06/23/2005

AGILENT TECHNOLOGIES
Legal Department, 51U-PD
Intellectual Property Administration
P.O. Box 58043
Santa Clara, CA 95052-8043

EXAMINER

SMITH, CAROLYN L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/772,723

Applicant(s)

WEBB, PETER G.

Examiner

Carolyn L. Smith

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 45-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 45-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1631

DETAILED ACTION

Applicant's amendments and remarks, filed 4/11/05, are acknowledged. Amended claims 1, 8, 47-48, and 51-52 and new claims 53-54 are acknowledged.

Applicant's arguments, filed 4/11/05, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

It is noted that the double brackets intended to delete the first mentioned "a" in line 7 of claims 1 and 8 do not contain the previous parentheses on either side of "a"; however, it is assumed that these parentheses were also intended to be deleted.

Claims 1-14 and 45-54 are herein under examination.

Claims Rejected Under 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF WRITTEN DESCRIPTION/NEW MATTER

Claims 1-14 and 45-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

Art Unit: 1631

convey to one skilled in the relevant art that the inventor, at the time of the invention was filed, had possession of the claimed invention.

The “providing” step in instant claims 1 and 8 can be interpreted several ways. While there is written support for a customer providing multiple vessels to the central fabrication facility (page 10, lines 18-22), there does not appear to be adequate written support in the claims, specification, and/or drawings as originally filed, for the broadest interpretation of this step which includes other parties performing the providing, such as the central fabrication station location providing the plurality of individual vessels. Applicants point to support on page 17, line 23, for the limitation of “using said map identifier to identify vessels corresponding to regions of the array”. While this section of page 17 (last paragraph) mentions an identifier on the array and using the identifier and map identifier to obtain the corresponding identity map for the array, it does not provide written support for “using the map identifier to identify vessels corresponding to regions of the array”, as stated in new claim 53. Applicants point to support on page 18 (lines 5-7) for the limitation of claim 54 reciting “wherein each of said vessels is marked with a unique identifier that is not composition information from that vessel”. This section of page 18 does not mention anything about marking vessels or that the identifier with no composition information. It is noted that negative limitations must have written support. Because there is a lack of written basis for the full scope of the providing step for amended claims 1 and 8, the phrase “wherein each of said vessels is marked with a unique identifier that is not composition information from that vessel” as stated in new claim 53, and the phrase “wherein each of said vessels is marked with a unique identifier that is not composition information from that vessel” as stated in new claim 54, filed on 4/11/05, these amended

Art Unit: 1631

limitations are considered NEW MATTER. Claims 2-7, 9-14, and 45-53 are also rejected due to their direct or indirect dependency from claims 1 and 8. This rejection is necessitated by amendment.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 and 45-54 are under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

These rejections are necessitated by amendment.

Claims 1 (line 3) and 8 (line 3) recite the phrase “providing a plurality” which is vague and indefinite. It is unclear who is doing the providing and to whom it is provided. For example, it is unclear if the receiver at the remote location(s) is performing the original providing or if the providing is coming from the place of array fabrication. Clarification of this issue via clearer claim wording is requested. Claims 2-7, 9-14, and 45-53 are also rejected due to their direct or indirect dependency from claims 1 and 8.

Claims 1 (line 5) and 8 (line 5) recite the phrase “each member” which is vague and indefinite. It is unclear if “each member” is referring to each vessel or each biopolymer (claim 1) or each set of biopolymers (claim 8). Clarification of this issue via clearer claim wording is

Art Unit: 1631

requested. Claims 2-7, 9-14, and 45-53 are also rejected due to their direct or indirect dependency from claims 1 and 8.

Claim 53 recites the phrase “corresponding to” which is vague and indefinite. It is unclear what criteria and to what degree these criteria must be met to be considered to be corresponding. Clarification of this issue via clearer claim wording is requested.

Claim 54 contains steps (a) through (e) separated by semicolons which is vague and indefinite. It is unclear if all 5 steps must be present or if only one must be present or various other scenarios. Insertion of the word “and” or “or” after the last semicolon would clarify this issue. Correction of this issue is requested via clearer claim wording.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 and 45-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunkapiller et al (P/N 5,942,609), in view of Zeleny et al. (P/N 6,215,894), Brown et al. (P/N 5,807,522), Anderson (P/N 6,456,942), Shakib et al. (P/N 5,812,793), and Balaban et al. (P/N 6,229,911).

This rejection is necessitated by amendment.

Art Unit: 1631

It is noted that the instant specification on page 9, lines 13-17, refer to “unique” as follows: “Each array 12 has associated with it a unique identifier in the form of a bar code 356 described below. By ‘unique’ in this sense does not mean the identifier is absolutely unique, but it is sufficiently long so as unlikely to be confused with another identifier on another tray (and is preferably unique as to a particular fabrication station on a given communication channel.”

Hunkapiller et al. describe creating arrays with addressable locations where multiple biopolymer samples can be fixed or mounted in fixed locations (col. 18, lines 11-21). Hunkapiller et al. describe liquid reagents being delivered from vessels to solid supports (col. 5, lines 10-12) which include addressable arrays (col. 9, lines 18-21), which represents obtaining and providing a plurality of individual vessels. Hunkapiller et al. describe placing vessels in cooling/heating zones, such as heating blocks, ovens, or chillers (col. 17, lines 63-66) which represents providing a plurality of vessels in a defined format, as stated in instant claims 1 and 8. Hunkapiller et al. describe assembly of a polynucleotide, including DNA, on a solid support (abstract and col. 6, lines 56-59). Hunkapiller et al. describe using solid supports having rigid or semi-rigid character as well as an array of physically separate regions on the support with wells (col. 8, line 64 to col. 9, line 7), which represents a format of a tray with multiple wells, as stated in instant claims 45 and 49. Hunkapiller et al. do not describe saving in a memory a map of the identity of the vessels corresponding to substrate regions where the biopolymers are deposited, applying the map identifier to the substrate or housing carrying the substrate, or shipping the fabricated array with applied map identifier to a remote location. Hunkapiller et al. do not teach the method of generating the array at a central fabrication station and making associated map identifiers that are communicated to physically remote stations and from the central fabrication

Art Unit: 1631

station. Hunkapiller et al. also do not teach the communication of the information via network (i.e., LAN (Local Area Network), WAN (Wide Area Network), e-mail, etc.) or computer readable storage media.

Zeleny et al. describe an identifier corresponding to each experiment imprinted on the biochip (col. 2, lines 13-14) which represents a portable storage medium. Zeleny et al. describe the identifier is machine-readable which is imprinted on the chip prior to deposition of the array experiment (col. 2, lines 18-20). Zeleny et al. describe a file is opened on a computer system where the operator may enter various parameters of the experimental array including a map of the reagents deposited in the array (col. 2, lines 20-25) which represents a format map of the individual identity of substances with regions on an array which would inherently be in correspondence with the vessels containing the identified substances, as stated in instant claim 53. Zeleny et al. describe a computer-stored record corresponding to each identifier (abstract) which is reasonably interpreted as a database. Figure 1 shows multiple wells of an array that are arranged in rows and columns, as stated in instant claims 46 and 50. Figure 1 shows numerical identifiers in which some of the digits identify experimental parameters, source of the array, and the array itself (tray number) (col. 3, lines 8-18), as stated in instant claims 47 and 51. Figure 2 further explains Figure 1 in greater detail with individually identified control spots (22) and array experiment spots (20) which represent identity of specific column and row numbers as well as unique format identifiers for each member wherein member is interpreted to be the substance, as stated in instant claims 1, 8, 47 and 51.

Brown et al. describe mass fabrication of microarrays (col. 2, lines 20-25) and shipment of DNA reagents via microarrays to researchers (col. 14, lines 36-42).

Balaban et al. teach that portable storage media may be used to carry information between computers (col. 6, lines 16-18).

Anderson describes a server that designs a set of probes to capture target sequences requested by a user, a synthesizer (fabrication station) that builds the probes on the surface of an array, and a chip that is shipped to a user (col. 2, lines 57-62). Anderson describes methods for interfacing computer technology via a network in a remote manner with biological and chemical processing and synthesis equipment (col. 1, lines 37-54). Anderson describes controlling and/or monitoring equipment for synthesizing or processing biological or chemical materials from a remote location (col. 2, lines 1-4). Anderson describes a remote location is linked via the Internet to an internal server or intranet (col. 2, lines 53-57). Anderson describes a display of the information about the chip in Figure 4 (col. 3, second paragraph). The figure on the front page of the Anderson patent displays arrows in a cyclical manner (continuous) which represents that this process may occur multiple times with the "array synthesis equipment" representing a central fabrication station.

Shakib et al. teach an asynchronous store and forward data replication system and the method utilizing existing computer networks and/or network control software as a transport agent to deliver the communication messages (abstract). Shakib et al. teach a system and method which can generate information from a remote station (i.e., creation of new data, modification of existing data, or deletion of existing data) (col. 3, lines 20-28), and communicate to another remote station over foreign networks such as the Internet or other Wide Area Network (WAN) (col. 5, lines 28-32). Shakib et al. teach the assignment of all data sets and individual objects which make up the data sets with unique IDs, allowing them to be tracked throughout the

Art Unit: 1631

network (col. 4, lines 39-46) and ID values (col. 8, line 23) which represents the individual identity of individual objects via identifiers relative to a reference mark as well as unique IDs for the vessels (individual objects) that are not composition information, as stated in instant claims 1, 8, 48, 52, and 54. Furthermore, Shakib et al. teach the access of privileged information via use of IDs of the data set (col. 4, lines 50-57). Shakib et al. teach data sets with identifiers and having a copy of data set objects as well as data set properties (or containers) associated with the copies of the data set objects (col. 4, lines 50-65).

Zeleny et al. state that analysis of raw data from a biochip array collected by a scanner was previously performed manually which involved significant operator time as well as errors in the scanning and analysis procedure (col. 2, lines 4-10). One of ordinary skill in the art would have been motivated to automate microarray biochip experiments, as stated by Zeleny et al. (col. 1, lines 5-9). Therefore, it would have been obvious to add automated techniques, beginning with automated delivery of liquid reagents from vessels to the array (as stated by Hunkapiller et al. (col. 5, lines 7-11), using barcode identifiers and mapping reagent location as stated by Zeleny et al. in order to avoid unnecessary errors and speed efficiency, as stated by Zeleny (col. 2, lines 4-10). Shakib et al. teach the ability of data or data sets (i.e., information) transfer from a remote station, such to another remote station and the ability to generate unique identifiers to track down and access the data or data sets. The ability to communicate, access, or exchange data through network, such as e-mail, WAN, LAN, the Internet, etc., would be advantageous since it would allow communication of any information (even an array design) between physically separate individuals, companies, or entities, quickly. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of

Art Unit: 1631

Shakib et al. as well as the distribution of microarrays (as stated by Brown et al.), array shipment and evaluated by user (stated by Anderson, col. 2, lines 61-67) and portable storage media use (as stated by Balaban et al.) to the above teachings to expedite the data transfer/access, or more specifically, array designs and any pertaining information thereof, to the array generation scheme, and thus avoiding wasted use of operator time and errors as previously stated by Zeleny et al.

Thus, claims 1-14 and 45-54 are obvious over the cited references.

Applicants state that following entry of the amendment, the claims clearly specify that each member is assigned a unique format identifier. It is noted that “each member” can be interpreted to be each vessel or each biopolymer. Applicants summarize their invention. Applicants state the combination of cited references do not teach assigning each member of a plurality of source vessels a unique format identifier and saving in a memory a map of unique format identifiers assigned to each original source vessel. While the claims may be interpreted in such a manner, it is noted that they can be interpreted with a broader meaning of unique format identifier and that “each member” is not necessarily referring to source vessels. Applicants summarize the cited references. Applicants state that Zeleny et al. do not physically identify the original source vessel relative to other vessels in the original plurality. This statement is found unpersuasive as the instant claims do not mention “physically” or “original source” referring to identification of vessels. Applicants state that the claimed identity map is the collection of unique format identifiers assigned to each vessel in the plurality that allows the customer to easily correlate the source vessels with the array. This statement is found unpersuasive as not all

Art Unit: 1631

of this information is stated in the claims and the written support in the specification appears to have an identity map for identifying the array, but not the vessels, per se (page 17, last paragraph). Applicants state that the cited references do not include all of the limitations of the instant claims. This statement is found unpersuasive because the rejection above states how each cited addressed the claimed limitations.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG

Art Unit: 1631

30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

June 14, 2005

Ardin H. Marschel 6/20/05
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER